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Application Possibilities of Traumeel® S Injection Solution: Results of a Multicentric Drug Monitoring Trial Conducted on 3,241 Patients

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Key words: Traumeel S injection solution, homeopathic ampoule preparation, application survey

Abstract

A drug monitoring trial conducted on 3,241 documented cases of therapy investigated the effectiveness, the patient tolerance, and the mode of application of a homeopathic ampoule preparation (Traumeel S injection solution). The study determined that arthrosis – especially cases of gonarthrosis and coxarthrosis – was the chief area of application for the homeopathic medication under examination. Within this area of indication, the study included detailed analyses of the mode and frequency of application of the preparation. In addition, patients suffering from myogelosis, sprains, periarthropathia humeroscapularis, epicondylitis, and tendovaginitis were also frequently among those treated with Traumeel S injection solution. Of all the patients, 47.0% received adjuvant medicamentous therapy, and 65% obtained non-medicamentous therapy which included massage, applications of heat and cold, and electrotherapy. In 78.6% of the treated cases, the results of therapy were formally assessed as "very good" or "good." The patients' tolerance to the preparation was good.

1. Introduction

There are of course many and various ways available to the physician to administer medicinal preparations. The most frequent mode of application – at least for outpatients – is, customarily, oral administration. In certain cases, however, it can frequently prove advantageous to administer medication by other means. Application by injection, for example, represents an effective alternative in cases such as the following:

- For patients who experience gastric intolerance to a particular medication.
- In cases in which resorption via the intestinal tract cannot be expected to prove effective.
- For cases in which the medicinally active agent must be applied directly at the point of the pathological process.

For many years now, injection of medicinal preparations has been a widely practiced form of administering medication, owing to a number of primary advantages of the injection form. First, there is the advantage of the rapid onset of therapeutic action. Secondly, a medicinal preparation can be applied by injection regardless of whether or not a patient has recently eaten – for cases in which digesting food would possibly interfere with resorption of the remedy when given by oral means. And especially when certain local therapeutic action of the medication represents a significant factor – e.g., in the case of chondroprotective medication which must be applied by intraarticular means – administration by injection is superior to all other possible forms.

A wide selection of homeopathic preparations has, furthermore, been available on the market in injection form for many years now, and has been employed in daily medical practice with good success. Within the context of homeopathic therapy, combination preparations such as Traumeel S injection solution have proved especially beneficial. This preparation is a combination remedy produced according to homeopathic manufacturing procedures. It is intended for the therapy of injuries, soft-tissue swelling, as well as inflammatory processes and degenerative disorders associated with inflammation as encountered among various organs – especially as they afflict the musculoskeletal system. In addition to a number of components of botanical origin – e.g., Arnica montana, Calendula, Hamamelis, and Millefolium – this preparation also contains homeopathic attenuations of mineral substances: Mercurius solubilis Hahnemanni and Hepar sulfuris. An ampoule preparation with very similar formulation was on the market for several decades under the same name (only without the suffixed "S"). A great number of reports from medical practice as well as from scientific studies have been published on this preparation and have in highly impressive manner verified the therapeutic effectiveness of this combination homeopathic medication [see references 1 - 16]. In 1989, slight modifications were made to the formulation of this preparation to accommodate the latest changes in official German stipulations for drug quality and drug safety.

The objective of the post-marketing drug surveillance reported below was to document the effectiveness and the tolerance of the preparation, in its modified formulation, under conditions of daily medical practice.

2. Methods employed in this survey

2.1 Conduct of the survey

A total of 348 physicians qualified in various specialty fields took part in the post-marketing drug surveillance. The participating doctors were instructed to record all relevant data on a standardized data collection form for each treated and documented case. In order to obtain as extensive an overview as possible of the entire possibilities of application of Traumeel S injection solution, no criteria of inclusion or exclusion were established as constraints for the patients who were to be admitted to the survey. The following data were documented:

- Age and sex of the patients.
- The nature of the traumatic, inflammatory, or degenerative affections which prompted application of the ampoule

preparation.
- Localization of the complaints.
- The duration of complaints before beginning treatment with the preparation.
- The type and frequency of application of the homeopathic ampoule preparation.
- The duration of therapy with the preparation.
- Adjuvant therapeutic measures.
- Description of undesired effects experienced.

The participating physicians enjoyed complete freedom in being able to prescribe – as they deemed necessary for each individual case – any adjuvant medicamentous or non-medicamentous therapy for treatment of the same affection for which Traumeel S injection solution was administered. The only requirement here, however, was that the physician record the type of such adjuvant therapy on the data collection form.

For purposes of assessment of the results of therapy, the following five grading categories were available for checking on the data collection form:

1 = "Very good": complete and long-term relief from complaints.
2 = "Good": definite, long-term improvement, or complete relief for a limited period of time.
3 = "Satisfactory": improvement for a limited period of time.
4 = "Unsuccessful": no change in complaints.
5 = "Worsening".

The physicians were requested to write a plain-text description of and undesired effects experienced.

This post-marketing drug survey was conducted from April until the end of November in 1990. A total of 3,467 data collection forms were filled out by the participating physicians and returned to the company Biologische Heilmittel Heel before 30 November 1990.

2.2 Preparation of data and statistical analysis

Of the entire 3,467 data collection forms returned, 226 (6.5%) failed to contain either data on the nature of the affection being treated, or indication of the success or failure of therapy. These data collection forms were considered as not amenable to evaluation and were therefore excluded from statistical analysis. It was possible, however, to acquire the data concerning undesired side effects from all submitted data collection forms, regardless of whether they were suitable for inclusion in general analysis.

The acquired data were analyzed with the aid of techniques used in descriptive statistics. Representation of the test data collected took place partially in the form of their basic statistical values (mean values and standard deviations), and partially by indication of their absolute or percent frequency distributions. Since not all questions were answered on all data collection forms, the indicated percent values do not always sum to 100%.

3. Results of the survey

3.1 Description of the patient population

Among the entire 3,241 patients included in the statistical evaluation, women (with 50.5%) were slightly more frequently represented than were men (49.1%). The mean age of the entire population was 47.5 years (standard deviation = ± 17.8 years). Among the male patients, there is a distribution peak in the age group 41 – 50, whereas the age distribution for women reaches its maximum point between 51 and 60. Fig. 1 depicts the distribution of age and sex for all cases with complete reported data on these two variables.

3.2 Diagnoses and duration of complaints

The physicians who participated in this drug monitoring trial administered the homeopathic ampoule preparation being studied for treatment of a variety of degenerative, traumatic, and inflammatory affections. The most frequent disorders treated were forms of arthrosis (primarily, gonarthrosis and coxarthrosis), followed in frequency by forms of myogelosis, and by sprains. Participating physicians also recorded a substantial number of the following diagnoses: periarthropathia humeroscapularis, epicondylitis, and tendovaginitis. For statistical analysis, the patients were broken down into eight symptom groups, in accordance with the disorders indicated on the data collection forms as requiring therapy. In order to distinguish clearly among these individual diagnosis groups, the breakdown into symptom groups included only those patients for whom not more than one symptom was recorded. All other patients – i.e., those for whom the physician recorded more than one symptom – were statistically assigned to a special group with the generic designation "Combination of different disorders." In addition, the group "Miscellaneous disorders" was also established: it contained all the less

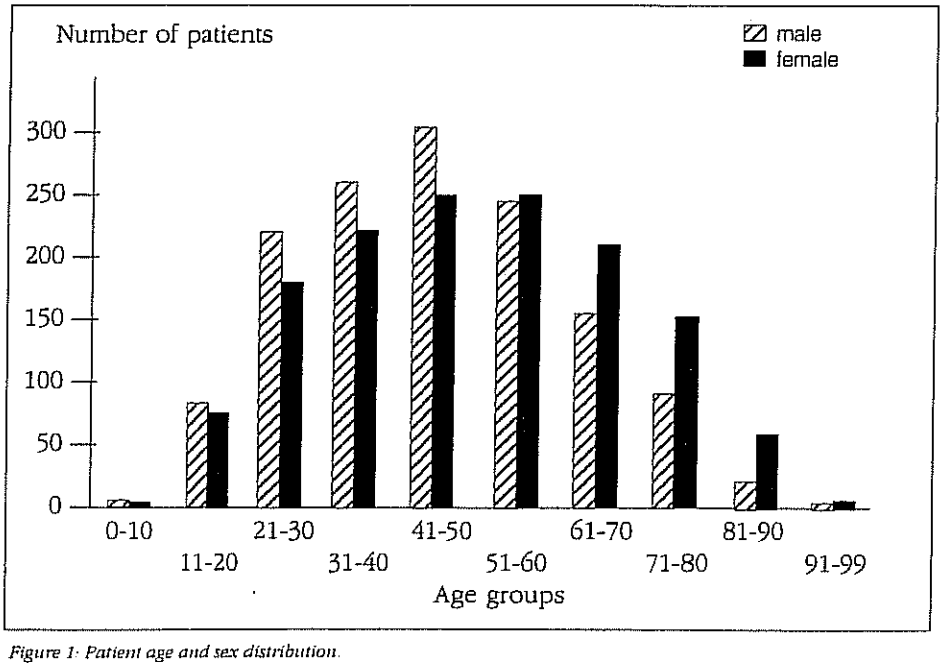

Figure 1: Patient age and sex distribution.

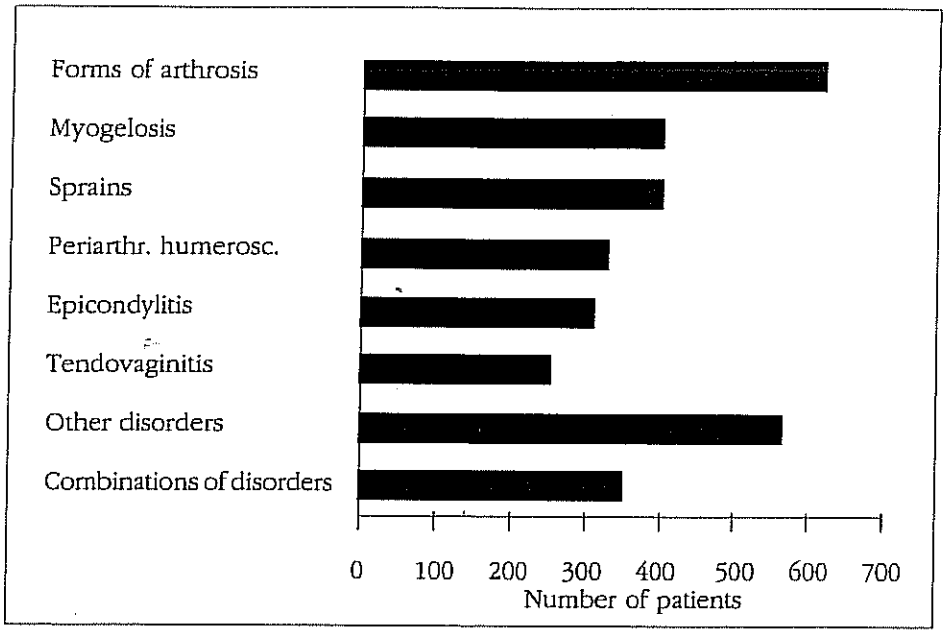

Figure 2: Number of patients who were treated with the ampoule preparation for the respective disorders (n = 3,241).

frequent individual diagnoses: i.e., all those single symptoms for which fewer than 150 cases were recorded. The miscellaneous group included the following: 143 patients with contusions, 116 patients with bursitis, and 87 with hematomas. In addition, there were numerous further diagnoses in this group: e.g., heel spur, intercostal neuralgia, styloiditis radii, and other disorders. Fig. 2 graphically depicts the number of patients recorded in the various individual diagnosis groups.

With reference to the entire patient population, 33.9% of all cases reported that they had suffered from their complaints less than one week before beginning therapy. Somewhat fewer – 31.0% of the patients – had suffered for more than one week, but for not more than one month. In 18.5% of the cases treated, the symptoms had persisted for a period between one month and one year. For 11.9% of cases, the patients had suffered between one and five years. A history of symptoms for more than five years was indicated by 3.3%.

There were considerable differences among the individual diagnosis groups with regard to how long the patients had suffered from the respective symptoms. For example, over 80% of the patients who received the homeopathic ampoule preparation for purpose of therapy of sprains had experienced their symptoms for less than one week. In conjunction with the diagnoses tendovaginitis and epicondylitis, on the other hand, duration of the symptoms was most frequent for a period between one week and one month. Patients with forms of arthrosis, moreover, reported extremely long prehistories of these disorders. Almost half of these cases (48.5%) were characterized by a term of complaints lasting between one and ten years.

Table 1 indicates for each individual diagnosis group the number of treated cases as well as the percent share of patients with a term of symptoms lasting longer than one week. The order of listing of the symptom groups in this table is according to the share of patients who had suffered from each symptom for longer than one week: i.e., diagnoses with generally brief previous duration are listed at the top of the table, with the sequence proceeding down-ward as the term of sickness increases. The column at the far right of this table, furthermore, indicates the most common location of traumatic or degenerative complaints.
In Table 2, a more precise breakdown of the symptom locations was provided within the patient group for forms of arthrosis. The data revealed that the most frequent form was gonarthrosis, followed by coxarthrosis. Arthrosis of the ankle, hand, and shoulder joints follows, in descending order of frequency. Table 2 indicates the absolute and percent frequencies of the various locations of complaints within the group of arthrosis patients.

3.3 Medication

On the basis of the entire test population, therapy took place exclusively with Traumeel S injection solution in 19.2% of the cases. For 80.3% of the patients, the participating physicians prescribed adjuvant medicamentous or non-medicamentous therapy. This additional therapy involved strictly non-medicamentous methods in 33.3% of the

Diagnosis	Number of patients	Percent of patients with duration of complaints > 1 week	Most frequent location of complaints
Sprains	400	16.7%	Ankle
Other disorders (Contusions, bursitis, hematomas, etc.)	568	40.7%	Knee
Tendovaginitis	251	64.5%	Forearm
Combinations of various disorders	357	64.7%	Combination of different locations
Myogelosis	403	73.2%	Neck/nape
Epicondylitis	309	79.9%	Elbow
Periarthropathia humeroscapularis	330	82.4%	Shoulder joint
Arthrosis	623	95.0%	Knee joint

Table 1: Kinds of disorders treated with Traumeel® S injection solution (in order of duration of the complaints).

Location of the arthrosis	Number of patients	Percent of total cases of arthrosis (n = 623)
Knee joint	347	55.7%
Hip joint	101	16.2%
Ankle	22	3.5%
Wrist	20	3.2%
Shoulder joint	17	2.7%
Other locations (incl. combinations)	116	18.6%

Table 2: Breakdown of arthrosis cases according to location of the disorder.

Type of adjuvant medication prescribed	Number of patients
Analgesics / antirheumatics	356
Antiarrhythmics	14
Antiphlogistics	42
Corticosteroids	12
Dermatics	4
Medication for common colds and flu	6
Local anesthetics	84
Muscle relaxants	11
Neural therapeutic agents	40
Agents for vein disorders / varicosis	36
Cytostatics	4
Series of preparations / homeopathic agents	57
Combinations of several medications	228
Other forms of administration of Traumeel® S	601

Table 3: Medicamentous forms of adjuvant therapy which were applied for more than 0.1% of the patients.

cases treated. The primary forms of such additional treatment included thermotherapy, cryotherapy, electro-therapy, and massage. Exclusively medicamentous therapy was applied for 14.9% of the patients, whereas combined applications of medicamentous and non-medicamentous adjuvant therapy was required for 32.1%. From the standpoint of the numerical prevalence of application, the chief types of medication prescribed on an adjuvant basis included analgesics, antirheumatics, as well as other forms of Traumeel S (i.e., the drops, tablets, or ointment). The physicians entered the names of the preparations on the data collection forms in plain text, and these medicinal products were then coded in accordance with the main-group listing in the The German Physician's Desk Reference. Table 3 provides an overview of the medication provided on an adjuvant basis.

The fraction of patients treated exclusively with Traumeel S injection solution was highest (27.0%) for the diagnosis "Sprains." On a purely numerical basis, however, combined forms of therapy were most prevalent. Table 4 lists the percent proportion of the various forms of therapy employed: monotherapy, medicamentous adjuvant therapy, as well as combinations of these types of therapy. The listing sequence of the diagnosis groups, from the top of the table to the bottom, corresponds to the frequency of conduct – in descending order of monotherapy with the ampoule preparation being tested.

Diagnosis	Therapy exclusively with the homeopathic ampoule preparation	Additional medicamentous adjuvant therapy	Additional non-medicamentous adjuvant therapy	Additional medicamentous and non-medicamentous adjuvant therapy
Sprains	27.0%	14.3%	34.5%	23.8%
Other disorders (Contusions, bursitis, hematomas, etc.)	25.9%	23.1%	25.9%	24.5%
Tendovaginitis	22.7%	15.5%	34.7%	26.7%
Epicondylitis	18.4%	12.9%	36.2%	31.7%
Arthrosis	16.2%	14.8%	32.1%	35.9%
Myogelosis	15.1%	9.4%	41.4%	34.0%
Combinations of various disorders	13.7%	13.4%	27.4%	44.8%
Periarthropathia humeroscapularis	13.0%	11.2%	39.1%	36.4%

Table 4: Subsets of patients treated with monotherapy and with various forms of adjuvant therapy, within the individual diagnosis groups.

Type of application	Gonarthrosis (n = 347)	Coxarthrosis (n = 101)	Arthrosis at other locations (n = 175)
Intra-articular	46.1%	25.7%	16.6%
Periarticular	19.9%	22.8%	13.7%
i.m.	10.6%	32.7%	30.3%
s.c.	4.9%	6.9%	11.4%
i.v.	0.9%	1.0%	4.6%
i.c.	0.6%	1.0%	1.1%
Other types of applications and combinations	17.0%	9.9%	22.3%

Table 5: Percent breakdown of the various types of application of Traumeel® S injection solution in the treatment of arthrosis at various locations.

Type of application	Daily application	Application 3 times a week	Application 2 times a week	Application once a week
Intra-articular	0.9%	11.6%	59.1%	25.1%
Periarticular	4.3%	23.3%	54.3%	13.8%
i.m.	19.5%	30.8%	39.8%	9.7%
s.c.	13.6%	13.6%	47.7%	20.4%
i.v.	8.3%	41.7%	25.0%	25.0%
Other types of applications and combinations	7.9%	23.0%	51.3%	14.1%

Table 6: Frequency of the application of Traumeel® S injection solution, in accordance with the types of application for arthrosis.

3.4 Frequency and mode of application of Traumeel S injection solution

Traumeel S injection solution was applied twice weekly for 40.1% of the patients. In 27.7% of the cases, physicians reported injection of the preparation three times a week. Weekly injections were applied for 13.6% of the patients, and 15.2% of the patients received daily administration of the injection solution. Relatively frequent applications were reported primarily in conjunction with the diagnosis "Sprains": 28.0% of these patients received daily injections. The smallest proportion of cases treated by daily administration was reported for forms of arthrosis, on the other hand: only 7.5%. For these disorders, the Injection solution was applied twice a week for more than half of the patients (51.5%).

Of all the various techniques of application of Traumeel S injection solution, intramuscular injection was relatively the most frequent: 24.0% of all cases treated. In second place was subcutaneous injection, with 17.8% – followed by periarticular application with 14.6%, and by intraarticular, with 10.6%. In a smaller share of cases, furthermore, Traumeel S injection solution was applied by peritendineal (7.0%), intravenous (4.3%), or intracutaneous (2.8%) means. Other possibilities of application – e.g., by intrabursal, paravertebral, or trigger-point administration – as well as combinations of the stated forms of application, occurred for occasional cases and represented an additional total share of 18.6% of the entire cases treated. There was note-worthy variation in the frequency of the individual modes of application among the various diagnosis groups. The diagnosis "Sprain" represented the greatest share of patients treated by intramuscular application of the homeopathic ampoule preparation: 41.0%. In cases of myogelosis, the greatest fraction of cases was treated with subcutaneous application of the preparation: 33.3%. Patients afflicted with periarthropathia humeroscapularis received periarticular injection of the homeopathic preparation as the most frequent form of medication: in 35.5% of total cases. Those with arthrosis underwent intraarticular treatment with the injection solution as the most prevalent method of administration: 34.5%.

Table 5 makes a further breakdown: into the percent shares of the individual application possibilities for the various forms of arthrosis: gonarthrosis, coxarthrosis, and arthrosis in other locations. These data reveal that the intra-articular mode of application is particularly often resorted to for arthrosis of the knee: 46.1% of gonarthrosis patients received therapy exclusively in the form of intra-articular injections. This proportion was also high for patients with arthrosis of the hip joint, for whom intra-articular injection was the only form of therapy in more than a quarter of the cases. Periarticular injection techniques were applied for approximately one-fifth of all arthrosis patients: most frequently for coxarthrosis patients (22.8%), somewhat less often for gonarthrosis (19.9%), and least frequently for arthrosis at miscellaneous locations (13.7%). The intramuscular injection of Traumeel S injection solution furthermore represented the therapy of choice for a significant share of the arthrosis patients.

Type of application	1 ampoule per injection	2 ampoules per injection	$^1/_2$ ampoule per injection
Intra-articular into knee joint	66.9%	30.6%	0.6%
Periarticular into the vicinity of the knee joint	75.4%	23.2%	-
Intra-articular into the hip joint	76.9%	23.1%	-
Periarticular in the vicinity of the hip joint	60.9%	34.8%	4.3%
Intra-articular into another joint	86.2%	6.9%	3.4%
Periarticular into the vicinity of another joint	79.2%	12.5%	4.2%

Table 7: Number of ampoules used per injection, in accordance with the application technique for various forms of arthrosis.

Other modes of application for arthrosis patients demonstrated relatively minor numerical significance in this study.

Analysis of the frequency of application for arthrosis patients as a function of the technique of application with the homeopathic ampoule preparation reveals the following: that intramuscular and periarticular injections were generally applied at shorter time intervals than were intra-articular injections of the same preparation. Whereas injections were administered more frequently than twice a week in 50.3% of cases in which physicians selected the intramuscular mode, and in 27.6% of cases in which periarticular techniques were used, intra-articular injections were administered more often than twice a week only in 12.5% of the cases. Table 6 depicts the number of injections performed per week as a function of the type of application.

This drug monitoring trial also provides data on the number of ampoules of Traumeel S injection solution administered per injection, with differentiation by intra-articular and periarticular means, and with breakdown for the various types of arthrosis (Table 7). For the intra-articular injection of Traumeel S injection solution into the knee joint for gonarthrosis patients, the participating physicians administered two ampoules per injection in almost one-third of the cases treated (30.6%). On the other hand, two ampoules were injected per therapy session for less than a quarter of cases (23.2%) involving periarticular injections into the knee. In the treatment of patients with coxarthrosis, in contrast, these relationships are reversed for the application of Traumeel S injection solution into the area of the hip joint. For coxarthrosis, two ampoules per injection were used for periarticular injection in more than one-third of cases, whereas the fraction of patients who received two ampoules by intra-articular administration of the preparation was only 23.1%. A clear majority of the participating physicians used one ampoule of Traumeel S injection solution to treat the various forms of arthrosis at other points on the body.

3.5 Duration of therapy with Traumeel S injection solution

With reference to the entire population of patients, the term of therapy with Traumeel S injection solution amounted to a period between one week and one month for the majority of patients (62.7%). For 15.9% of the patient population, the therapy with the homeopathic ampoule preparation lasted less than one week. In 15.2% of the cases, the term of therapy amounted to 1 – 3 months; in 3.2%, up to 6 months; and in 2.1%, more than 6 months. Separate analysis of the term of therapy for the various diagnoses reveals that the fraction of patients with a term of therapy less than one week was highest for patients being treated for sprains: 34.8%. The drug monitoring trial also disclosed that the longest durations of treatment were for arthrosis. For these patients, the proportion with a term of therapy of less than one week was only 2.2%, whereas 46.4% of this group required treatment with the homeopathic ampoule preparation for a period longer than one month.

3.6 Assessment of therapy results

Overall analysis of the results achieved in therapy – with the entire patient population as basis – reveals that, in 78.6% of the cases, the results were either "very good" (complete and long-term relief from complaints) or "good" (definite, long-term improvement, or complete relief for a limited period of time). In addition, 17.8% of the patients demonstrated "satisfactory" results: improvement for a limited period of time. Only for 3.5% of the cases was the therapy assessed as "unsuccessful" (no change in complaints). Five patients reported worsening of complaints during the same period during which the preparation was administered. Fig. 3 represents the percent breakdown among these therapy-result evaluations for the entire patient population.

Analysis of the results of therapy according to the various diagnosis groups reveals that either very good or good results were most frequently observed for the treatment of sprains: 95.0%. Table 8 provides a ranking for the evaluations "results of therapy very good or good" for the various diagnosis groups. From top to bottom of this table, the figures reveal the descending order of therapy success which was assessed as good or better.

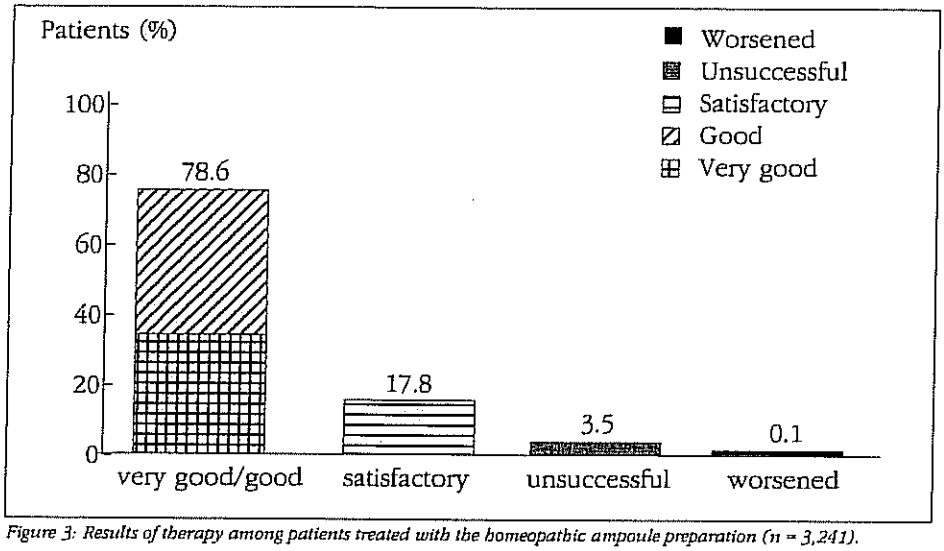

Figure 3: Results of therapy among patients treated with the homeopathic ampoule preparation (n = 3,241).

Upon comparison of results of treatment among patients who received adjuvant therapy and those who did not, it is noteworthy that the findings were more positively assessed for cases with exclusive administration of Traumeel S injection solution, as compared with therapeutic results for combination therapy which featured adjuvant medicamentous or non-medicamentous treatment in addition to the homeopathic ampoule preparation. The share of very good or good results was 85.2% for sole administration of Traumeel S injection solution, 82.8% for prescription of adjuvant medication, and 79.6% for application of non-medicamentous adjuvant measures. For those cases in which medicamentous and non-medicamentous treatment was combined, good or very good therapeutic results were achieved in 71.7% of the cases. Although these figures may seem paradoxical at first glance, the highly probable explanation lies in the fact that those cases for which adjuvant therapy was necessary generally represented patients with more severe symptom complexes. Their disorders were, as a result, more difficult to influence by therapeutic means.

Diagnosis	Number of patients with this diagnosis	"Good" or "very good" therapy results (% of the patients with this diagnosis)
Sprains	400	95.0%
Other disorders (Contusions, bursitis, hematomas, etc.)	568	87.1%
Tendovaginitis	251	86.9%
Myogelosis	403	80.1%
Epicondylitis	309	78.6%
Combinations of various disorders	357	75.6%
Periarthropathia humeroscapularis	330	74.8%
Arthrosis	623	59.5%

Table 8: Ranking of the good and very good therapy results in accordance with the diagnoses.

On the other hand, the relatively high proportion of good and very good therapeutic results for exclusive administration of Traumeel S injection solution can also be interpreted as an indication for the therapeutic effectiveness of this preparation. Indeed: for the patient subset consisting of 623 treated cases who received only Traumeel S injection solution – and who made up just under 20% of the entire patient population – the documented results of therapy could not of course have been contributed to or otherwise influenced by adjuvant treatment.

Evaluation of the results of therapy in their relation to the frequency of application of Traumeel S injection solution reveals that the fraction of good or very good results is greater in conjunction with administration at short intervals, than for application with longer periods between injections. Whereas good or very good therapy success was achieved in 68.2% of cases in which application was one injection per week, this same degree of success in therapy was 75.3% for patients with two injections per week, and was 82.8% for cases treated with three injections weekly. For daily application of the homeopathic ampoule preparation, good or very good therapy results were possible for 90.1% of the patients treated.

This evident relationship between the application frequency of the preparation and the outcome of treatment can also be interpreted as further evidence of the therapeutic effectiveness of the homeopathic preparation.

Since the physicians participating in this drug monitoring trial used various techniques for application of the ampoule preparation being studied, analysis is possible of the degree to which the method of administration influences the therapeutic success of the preparation. Table 9 depicts these data. They reveal that the percent of good or very good therapy results is highest for intravenous injection, and lowest for intra-articular application.

At the same time, these relatively unfavorable findings for the intra-articular mode should not necessarily be interpreted as evidence that this technique of administration is inappropriate for therapeutic employment in this context. The following fact should additionally be taken into account in evaluating these

Type of application	Number of cases	Successful quota (very good and good)	Unsuccessful quota (unsuccessful and worsened)
i.v.	138	87.0%	2.9%
i.c.	90	83.4%	2.2%
s.c.	576	81.6%	3.8%
i.m.	779	81.4%	3.0%
Peritendineal	228	85.5%	2.2%
Periarticular	474	77.2%	4.0%
Intra-articular	343	66.5%	6.1%
Other types and combinations	604	74.9%	3.3%
No data given	9	77.7%	11.1%

Table 9: Therapy results for various types of application of Traumeel® S injection solution.

Types of application	Gonarthrosis as area of indication	Coxarthrosis as area of indication	Arthrosis at misc. locations as area of indication
Intra-articular application			
Number of cases	160	26	29
Therapeutic success quota (good and very good)	58.8%	65.4%	55.2%
Periarticular application			
Number of cases	69	23	24
Therapeutic success quota (good and very good)	62.3%	52.2%	62.5%
Other types of application (totaled)			
Number of cases	118	52	122
Therapeutic success quota (good and very good)	56.8%	61.5%	61.5%

Table 10: Therapy results for various application techniques of Traumeel® S injection solution, with respect to the various forms of arthrosis treated.

data: intra-articular injection is employed primarily for treatment of forms of arthrosis, i.e., within an indication area in which the general level of therapeutic success is in any case definitely lower than that for other disorders of the musculoskeletal system. In order, therefore, to enable more accurate evaluation of the therapeutic results obtained through intra-articular injection of Traumeel S ampoules within the particular indication area of arthrosis, data on the outcome of therapy has been presented in Table 10 – which shows breakdown according to the various types of arthrosis, and which includes comparison with the percent success data from other possibilities of application. This mode of representation reveals that the intra-articular technique of injection enabled better results – both for arthrosis of the knee as well as of the hip – than the "other techniques of application" – a category which includes intramuscular, intravenous, and subcutaneous forms of injection. Surprisingly, the percent of patients treated with good or very good success is even higher – especially for coxarthrosis – precisely when therapy was provided in the form of intra-articular application, than it is for coxarthrosis cases treated with periarticular injection. At the same time, though, Table 10 also provides evidence of how favorable therapeutic results can likewise be, when provided by periarticular injection – which enabled quite effective outcomes especially for gonarthrosis and arthrosis in "miscellaneous" locations.

3.7 Tolerance of Traumeel S injection solution

This drug monitoring trial evidenced that patient tolerance to Traumeel S injection solution can be evaluated as good. From the entire 3,467 cases treated with this preparation, there were only 19 reports of undesired side effects in conjunction with administration of the medication. In 8 cases, the side effects involved local reddening of the skin at the points of injection. This redness – associated in some cases with itching or burning – may be interpreted as an

allergic reaction to the preparation. One patient complained of a brief condition of pain in the musculus deltoideus after periarticular injection in the area of the shoulder joint. Three patients described transient irritation of the knee joint after intra-articular administration of the preparation. In one of these three cases, development of effusion was observed. One additional patient complained, after intra-articular application, of pain at the point of injection – without, however, evidence of further signs of local irritation. Three patients reported a sensation of heat after application of the preparation. There was one case of each of the following after administration: circulatory insufficiency, general feeling of unwellness (malaise), and fatigue. Particularly for patients with subjective complaints such as these last three cases, however, it is necessary to consider the patient's psychological situation which prevailed when the injections were applied. Some patients fundamentally react with feelings of anxiety or rejection to this kind of therapy, simply on the basis of the fact that the injections may prove painful. As a result, it is possible in particular individual cases for such circumstances to provoke physical symptoms.

4. Interpretation of survey results

Drug monitoring trials offer the possibility of investigating the tolerance of patients to medicinal products already on the market, and of gaining insights at the same time into the possibilities of employing the preparations in daily medical practice. These surveys can aid in determining the primary fields of application within the indication area of a preparation: an important factor, for example, in establishing test indications for clinical testing procedures. They are also valuable in documenting normally recommended doses, types of application, the duration of therapy, as well as expected therapy results achieved under conditions of actual practice.

The homeopathic ampoule preparation investigated in this drug monitoring trial is characterized by a broad range of possible applications, with primary area of effective administration in the field of orthopedic therapy. Comprehensive use has been made of Traumeel S injection solution particularly for degenerative joint disorders – i.e., forms of arthrosis – as well as for conditions of irritation – inflammation in connective tissue near joints: i.e., periarthropathia humeroscapularis, epicondylitis, and tendovaginitis. In addition, this preparation is also effectively suited for therapy of posttraumatic conditions (e.g., sprains): a conclusion based on documentation of therapy results from 400 treated cases in this survey.

Physicians participating in this survey employed the ampoule preparation Traumeel S injection solution either alone, or in conjunction with various adjuvant medicamentous or non-medicamentous forms of therapy, according to the severity of the individual disorders requiring treatment. Upon comparison of therapy results for patients who were treated exclusively by means of the preparation being investigated, with the results obtained from combined therapy, it appears upon initial examination of data that greater effectiveness could be expected for therapy exclusively with the homeopathic ampoule preparation. Consideration must be taken of the fact, however, that the participating physicians established an individual plan of therapy for each patient, and that selection of adjuvant therapeutic measures, as a matter of course, depended on the severity of the disorder requiring treatment. Consequently, the conclusion is not warranted that therapy of the disorders included here is generally more successful on the basis of treatment solely with Traumeel S injection solution.

On the other hand, the relatively good results of therapy which were documented for exclusive administration of this homeopathic ampoule preparation can to a certain extent be considered as valid evidence for the effectiveness of the tested preparation. In addition, the great proportions of good or very good therapy results for patients with frequent application – as compared to the outcomes with cases in which the preparation was less often applied – justify the conclusion that the homeopathic ampoule preparation in fact provided a positive contribution to the success of the therapy for the cases treated and documented in this trial. The drug monitoring trial conducted here confirmed the established reputation for good patient tolerance of Traumeel S injection solution. The frequency of undesired side effects with this preparation was very low, and the great majority of the few undesired reactions reported were minor in degree. The causal relationship between application of the preparation and appearance of the described reactions must, furthermore, be considered questionable in a number of these cases. The following conclusion is therefore warranted: that the homeopathic ampoule preparation investigated here may be considered a low-risk therapeutic agent for treatment of the consequences of traumata, as well as for therapy of inflammatory and degenerative processes afflicting the musculoskeletal system.

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